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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,557	08/22/2001	Erik Gunther	GUNE117293	8854

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EXAMINER

MARSCHER, ARDIN H

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,557

Applicant(s)

GUNTHER, ERIK

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 5,12-17 and 22-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-9,18-21,32, & 34-37 is/are rejected.
- 7) ☒ Claim(s) 3,10,11, & 33 is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 3/8/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

ELECTION BY ORIGINAL PRESENTATION

Newly submitted claims 26-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The methods as previously set forth and elected require three expression profiles as well as comparison of the third expression profile with the first and second profiles in contrast to claims 26-31 wherein independent claim 26 utilizes only a first and second expression profile for analyte identification. Thus the search for the previously set forth invention is directed to a 3 profile invention whereas a 2 profile invention is a large body of art which presents an undue search burden if added at this time thus supporting both the distinctness of these inventions as well as the undue search burden if searched together.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-31 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 6-9, 18-21, 32, and 34-37 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Daniel et al. (P/N 6,368,794).

This rejection is reiterated and maintained from the previous office action, mailed 1/14/04. Applicants argue that Daniels et al. does not disclose treatment with an analyte of previously uncharacterized specific pharmacological activity and that Daniels does not disclose the identifying of such an analyte via comparing expression profiles to a profile which is more similar to a specific expression profile. In response to the first argument a previously uncited sections of Daniels et al. is hereby set forth in column 1, lines 33-38, wherein the identification of polynucleotides is set forth involving diseases, such as cancer. Further discussion of such identification is set forth in column 1, line 55, through column 2, line 42. Such identification is reasonably interpreted to be directed to previously uncharacterized analytes as instantly claimed which are associated with cancer etc. Their potential usefulness in disease treatment is reasonably identification for specific pharmacological activity as required in the instant claims. This is further supported in the reference in column 11, line 59, through column

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14, line 11, wherein identified previously uncharacterized polynucleotides are applied in treatment methods. In response to the second argument Daniels et al. in column 5, line 4, through column 7, line 48, where the identification of polynucleotides of interest are correlated to particular cancerous disease tissue states and selected thereby. This correlation of profiles is reasonably the determination of a profile comparisons that are more similar to specific expression profiles wherein this similarity results in polynucleotide identification. As noted above polynucleotides identified in the methods of Daniels et al. also are potential compounds useful for expression profile altering activity during treatment methods against diseases such as cancer.

CLAIM OBJECTIONS

Claims 3, 10, 11, and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

May 28, 2004

Ardin H. Marschel 5/28/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER